Statement to
United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health
Subcommittee on Environment and Hazardous Materials

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October 20, 2005

Good morning. Thank you for this opportunity to testify before your combined subcommittees, and for your attention to the crucial issue of methamphetamine abuse in America.

As the manufacturer of Sudafed, the largest pseudoephedrine (PSE) brand in the U.S., Pfizer has long been involved in the fight against meth abuse. In the 1990s, we supported federal sales regulation and packaging guidelines for PSE. In 2002, we were the first in our industry to support even tougher state-level limits on the amount of PSE that consumers could purchase per sale. We have funded and been engaged in developing "meth watch" programs in over a dozen affected states. And this year, we introduced the first major PSE-free cold medicine – Sudafed PE – to American consumers.

Over time, despite the valiant efforts of law enforcement, the work of manufacturers and retailers, and the efforts of state legislators, we have seen America's meth crisis continue to deepen. In the face of this challenge, we at Pfizer have concluded that comprehensive action, including federal legislation to place all PSE products behind-the-counter, is a necessary part of any comprehensive strategy to combat meth abuse and the proliferation of small toxic meth labs.

Setting aside the details of implementation for a moment, we seem to be approaching a national consensus on how best to address America's methamphetamine problem. Taken together, bipartisan bills introduced in the House and the Senate point to the need for a comprehensive approach that will restrict access to PSE at the point of sale, control the importation of PSE into the United States, and adequately fund law enforcement, treatment, and education efforts. Pfizer supports all these approaches. We view the different bills now under consideration by the House, with some modifications, as fully compatible and complementary approaches to addressing the multi-faceted problem of meth abuse.

Pfizer has long taken the position that we need to strike the right balance between making medicines available to legitimate consumers and restricting access to criminals who would use our medicines for illicit purposes. Today, I would like to focus my comments on the principles that we believe should guide legislation, particularly regarding limits on the sale of PSE to consumers:

- Establish a single national standard restricting PSE sales to "behind the counter" in pharmacies, and perhaps certain other retailers;

- Oppose the classification of PSE as a Schedule V controlled substance;

- Regulate all forms of PSE equally -- including solid-ingredient tablets, combination products, liquid gel caps and liquids -- since the DEA confirms that all can and are being used by criminals to make meth;

- Impose national gram or package limits on the amount of PSE that can be purchased by an individual;

- Allow for a phase-in period, until January 2007, to give retailers adequate time to adjust to new restrictions;

- Fully fund anti-meth enforcement, education and treatment programs, including tough criminal statutes and import controls;

- Pre-empt divergent state and local laws and apply a single national standard.

Behind the counter… but not Schedule V

Theft of PSE from store shelves has been a source of supply for criminals. Where PSE has moved behind the counter, criminals have found it much tougher to get their hands on it, and local meth lab busts have dropped. Many who initially were skeptical of these laws, and to be fair that included many of us in industry, now accept that putting PSE behind the counter is an effective part of a comprehensive anti-meth strategy.

Pfizer believes that Congress should mandate that PSE be sold from "behind the counter," either the pharmacy counter or more broadly, but that designating PSE a Schedule V controlled substance is the wrong way to achieve this end. The reason is that Schedule V has unintended side effects that would impose unnecessary restrictions on consumers, medical practitioners, and industry, while doing little or nothing to keep PSE out of the hands of determined criminals.

For example, Schedule V can trigger "by prescription only" provisions in up to 19 states, which would make it necessary for consumers to visit or contact a doctor every time they feel a cold coming on and want to buy a medicine containing the decongestant they have relied on for years. The added inconvenience and expense of requiring a prescription for PSE is unreasonable in an environment in which PSE already is behind the counter. The same can be said of security and storage requirements that pertain to Schedule V drugs only.

Another unintended side effect of "Schedule V" is that *prescription medicines* containing PSE as an active ingredient (such as the "D" formulations of Rx allergy medicines) would be caught up in the nationwide Schedule V net. In some states, this would mean that mid-level medical practitioners, such as qualified RNs, could no longer prescribe these medicines, and doctors could no longer give them as samples to patients. Since, by definition, prescription medicines already can be dispensed only by a licensed pharmacist, the additional burdens of imposing Schedule V restrictions on Rx medicines are entirely unnecessary.

Moreover, under Schedule V, PSE sales would be limited to behind the pharmacy counter only. If Congress decides to allow sales somewhat more broadly, Schedule V does not offer that flexibility.

If, however, Congress nonetheless decides to designate PSE a Schedule V controlled substance, provision should be made in the legislation to limit the unintended side effects of the law by: (1) exempting Rx products, (2) including clarifying language that avoids triggering state "Rx only" statutes for Schedule V drugs, and (3) exempting PSE from Schedule V security and storage requirements.

Regulate the entire category equally

If Congress decides to put PSE products behind the counter, as we believe you should, then the entire category should be included for the simple reason that all formulations of PSE now on the market can be converted into meth. The only possible exception might be certain pediatric products that simply do not contain enough PSE to make theft worthwhile.

Pfizer manufactures or sells all forms of pseudoephedrine: single ingredient tablets, combination ingredient tablets, liquid-filled capsules, and liquids. If we believed that any one of these were particularly resistant to conversion into methamphetamine, we would request that you exempt it. Unfortunately, we know differently.

The June issue of the DEA *Microgram Bulletin* reports the results of two studies, one by the Washington State Patrol Crime Laboratory, and one by an independent forensic laboratory on behalf of McNeil Consumer and Specialty Pharmaceuticals. Both studies produced methamphetamine from liquid filled capsules and liquids using approaches similar to small toxic labs. These findings accord with a study prepared by another outside laboratory for Pfizer, which extracted PSE from liquid-filled capsules and liquids using a recipe found in a book available through a popular on-line store. A study by the DEA's North Central Regional Laboratory in Chicago had a similar result.

According to the Office of National Drug Control Policy, word already is out "on the street" in Oregon that liquids and gel caps can be converted into meth, and both have now been found in local labs. Criminals will use the products and methods they are familiar with, and switch to others if those no longer are available.

It is true that most – though not all – states have exempted liquids and gel caps from their anti-meth legislation. Were Congress to do so, however, there would be wide ranging consequences. A national exemption for liquids and gel caps would create an incentive for the entire industry to switch its manufacturing to those products – products that we know can be made relatively easily into meth. Inevitably, criminals everywhere would catch on, and we all would have wasted even more time in getting a handle on the problem of local toxic meth labs.

If, however, Congress includes all forms of PSE in legislation, you instead will create incentives for companies to develop and switch to non-PSE alternatives, an effort in which Pfizer has been engaged for many years. An implementation date of January 2007 would give these companies and retailers the time they need to prepare.

The search for solutions

Mr. Chairman, I have a story to share that we rarely have discussed publicly, the story of our ultimately unsuccessful efforts to develop a form of PSE that could not be converted into meth. What we called "Lock II" technology was an attempt to bind PSE with other chemicals that would prevent extraction and conversion. Over a period of years and an investment of millions of dollars, we developed a product that we believed could not be converted by local labs into methamphetamine. To be sure of what we had, we asked the DEA to give it their best shot to break the formula using street methods. What they told us came as a surprise: Lock II *could* be broken using a chemical increasingly employed by local meth cooks. While our Lock II technology would have been tough to crack (many times harder than liquids or gel caps), it was vulnerable. We understood that to switch our own line -- and potentially an entire industry -- to the new technology would succeed only in pushing the problem down the road. We were and are interested in permanent solutions.

As it became clear that the technical solutions we developed were impractical, Pfizer set about pursuing another plan. We decided to replace, and in some cases supplement, our PSE containing medicines with a new line of products containing phenylephrine (PE) as the decongestant ingredient. While PE is FDA approved, American consumers had limited exposure to it. To get a better idea of acceptability, we ran consumer tests in the U.S. that showed no statistical difference between PSE and PE in terms of consumers' perceptions of symptom relief.

Last January, we introduced our first PE product, Sudafed PE. We have since switched other Sudafed, Actifed and Benadryl products from PSE to PE, and by early next year we expect to have most of our brand lines switched over. As we hoped and expected, we have started a trend. Private label (store brands) quickly followed our lead. And we are pleased to see that one of our major competitors has just replaced its popular day and night cold medicines with "pseudoephedrine-free" formulas, one of which contains PE. We understand that another competitor may be about to follow suit.

Even without legislation, a number of major retailers including Wal*Mart and Target have voluntarily moved some or all PSE behind the counter. It is clear that the U.S. is moving toward a new paradigm in the cold and sinus category: PSE behind the counter, "PSE-free" in front of the counter. The argument that moving PSE behind the counter will unduly restrict access to cold medicines may have been true two years ago. It is no longer true today, and will be less so moving forward. The fact is, between the efforts of Pfizer and our competitors, and America's forward-thinking retailers, consumers soon will have a plethora of "PSE-free" medicines available on the store shelf. For those who still prefer PSE, as some consumers undoubtedly will, all they will have to do is ask for help in getting the medicine they need.

Why federal action makes sense

At latest count, more than thirty states have passed some form of PSE restrictions, and over half the remaining states have legislation pending. Restrictions range from Schedule V, which is interpreted differently in different states, to gram or package limits, to menus of options for display and sale of PSE containing medicines. This patchwork quilt of state regulations is precisely why federal legislation is necessary. Ideally, federal legislation will pre-empt state laws, leaving a predictable legislative environment that allows retailers, manufacturers, and consumers to plan and engage in commerce without undue burden. Legislation in the absence of preemption might have the salutary effect of dampening down legislative activity in the states for awhile, but it would leave in place many divergent laws, and the prospect of more changes to come. It would be preferable, from our point of view, to solve the problem once.

The opportunity before us

There are a number of other issues that undoubtedly will be addressed today by my fellow panel members. How many grams or packages of PSE should be allowed per sale or per month? Should non-pharmacies be allowed to carry PSE products behind the counter, and what specific security arrangements might be needed? Should single-dose packets be sold in airports and other transit locations? These are all important issues, and I will be happy to comment on them during questioning.

Whatever differences may exist over details, however, we should not lose sight of the fact that a historic opportunity is at hand. Strong bi-partisan coalitions in the House and Senate have endorsed action. Law enforcement, the drug control community and industry stand behind you. We at Pfizer are pledged to do all we can to assist your efforts to take meaningful, comprehensive action to fight meth abuse. We look forward to working with you and to answering your questions.